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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,498	03/02/2007	Michael Frass	FRZ-106US	9870

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EXAMINER	
STOUT, MICHAEL C	

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3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,498	FRASS ET AL.	
	Examiner	Art Unit	
	MICHAEL C. STOUT	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,3,9-11 and 18-24* is/are pending in the application.

4a) Of the above claim(s) *22-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *2,3,9-11 and 18-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2, 3, 9-11 and 18-21, drawn to a biopsy device, classified in class 600, subclass 567.

II. Claims 22-24, drawn to a biopsy device, classified in class 604, subclass 187.

Newly submitted claim 22-24 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Inventions I and II are directed to related products. The related inventions are distinct if: (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed Invention I cites a ventilation means formed by an overlow channel which is formed a distance form the syringe bottom in the inner wall of the cylinder, wherein the length of the channel make sit possible that the volume between the bottom and the plunger can be temporarily connected with the interior of the cylinder that is located above the plunger via at least one overflow channel, Invention II cites a ventilation cutout having a length, and Invention II further cites a plunger having a single piston disposed in the cylinder wherein the face has a depth less than the cutout and the cutout extends through the

cylinder wall. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 22-24 withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caillouette (US 5,651,372) in view of Bachynsky (US 5,971,953).

Caillouette discloses a device for needle biopsy adapted for aspiration of tissue specimens with a syringe cylinder (see Abstract), with a plunger displaceable therein as well as with a needle means (See Abstract and Figure 1), wherein the needle means has at least one needle (A hollow needle or cannula 18 is mounted on the forward end of the barrel in a conventional manner, Column 2, lines 40-48), whose channels open into the interior of the cylinder (best shown in Figure 1), and a ventilation means (aperture 20), which is formed at a distance from the syringe bottom in the inner wall of the cylinder (see Figure 1 and Column 2, Lines 49-62), wherein the ventilation means makes it possible a volume between the bottom and the plunger with a volume of air located behind the plunger thereby releasing the vacuum i.e. the vacuum generating space in the cylinder and the atmosphere located behind the piston.

Caillouette teaches the fundamental concept of providing a ventilation means to allow fluid to bypass a syringe plunger piston. Caillouette fails to disclose the ventilation

means is formed by at least one overflow channel wherein the length of the channel in the direction of the cylinder axis makes it possible that the volume between the bottom and the plunger can be temporarily connected with the interior of the cylinder that is located above the plunger via at least one overflow channel.

Bachynsky teaches means for permitting fluid to bypass a piston head comprising a ventilation means is formed by at least one overflow channel (Figure 2 shows an enlarged diameter section 25 with a plurality of overflow channels), which is formed at a distance from the syringe bottom in the inner wall of the cylinder (formed some distance form the needle end of the syringe, see Figure 1), wherein the length of the channel in the direction of the cylinder axis (see Figure 2) makes it possible that the volume between the bottom and the plunger can be temporarily connected with the interior of the cylinder that is located above the plunger via at least one overflow channel (see Figures 3-5).

Both Caillouette and Bachynsky teach devices for permitting fluid to bypass a syringe piston.

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device taught by Caillouette by substituting the piston bypass means disclosed by Caillouette for the piston bypass means taught by Bachynsky in order to release a vacuum from the syringe to once an adequate sample has been obtained and allows for the sample to be withdrawn while the sample is in the needle, see Caillouette Column 2, Lines 49-67.

Claims 2, 3 and 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caillouette (US 5,651,372) in view of Bachynsky (US 5,971,953) as applied to claim 18 above and in further view of Chin et al. (US 5,415,182).

Regarding claim 2, Caillouette/Bachynsky teaches the device for needle biopsy in accordance with claim 18 as set forth above. Caillouette fails to discloses the device, wherein the device has a said stop means, which limits the depth of penetration of the needles into the body in a defined manner.

Chin discloses a device, wherein the device has a stop means (sheath 106), which limits the depth of penetration of the needles into the body in a defined manner (see Column 5, Lines 23-34).

Both Caillouette and Chin teach biopsy devices.

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device taught by Caillouette to include a stop means as taught by Chin in order to control the depth of the tissue specimen, see Chin Column 5, Lines 23-42.

Regarding claim 3, Caillouette/Chin further teaches wherein a spacer (sheath 106 which performs several functions, see Column 5, Lines 23-42), which has holes associated with the at least one needle and can be pushed over the needles at least one needle in order to limit the depth of penetration into the body, is provided at least as a stop means (see Figures 1, 4 and 6).

Regarding claim 19, Caillouette fails to disclose the device wherein the needle means has a plurality of puncture needles.

Chin teaches a biopsy device comprising a plurality of needles, (see Figure 1).

Both Caillouette and Chin teach biopsy devices.

Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device taught by Caillouette to include a plurality of needles as taught by Chin in order to help diagnosis in certain applications, see Chin Column 2, Lines 32-47.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caillouette (US 5,651,372) in view of Bachynsky (US 5,971,953) and Rieck (US 2,551,902).

Caillouette fails to disclose the device for needle biopsy in accordance with claim 18 wherein a common protective sleeve, which can be attached by plugging to the syringe cylinder over the needles, is provided for all needles.

Rieck teaches an injection device comprising a common protective sleeve (sleeve 42, see Figure 2), which can be attached by plugging to the syringe cylinder over the needles (is frictionally mounted about the cup, see Figure 2 and Column 2 Lines 42-46), is provided for all needles.

Both Caillouette and Rieck teach needle devices. Thus it would be obvious to a person of ordinary skill in the art at the time of the invention to modify the device disclosed by Caillouette to include a protective cap over the needles as taught by Rieck in order to protect the device while being transported or handled, see Rieck Column 2, Lines 42-46.

Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caillouette (US 5,651,372) in view of Bachynsky (US 5,971,953) and Dejter, Jr. et al. (US 5060658).

Caillouette fails to teach the device for needle biopsy in accordance with claim 18 wherein a filter means is arranged in the path between the opening of the channels into the tips of the needles and the interior of the syringe cylinder, wherein the filter means comprises individual filter inserts in the tip-side end area of the needles.

Dejter teaches a device wherein a filter means (filter 22, see Figure 12) is arranged in the path between the opening of the channels into the tip of each of the at least one needle and the interior of the syringe cylinder (see Figure 4), wherein the filter means comprises individual filter inserts in the tip-side end area of the at least one needle (see Figure 12 and 13, and Column 9, Lines 60-68).

Both Caillouette and Dejter teach biopsy devices. Thus it would have been obvious to a person of ordinary skill at the time of the invention to modify the device disclosed by Caillouette to include an individual filter insert as taught by Dejter in order to ensure the same remains inside the storage portion of the needle, see Dejter Column 9, Lines 60-68.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caillouette (US 5,651,372) in view of Bachynsky (US 5,971,953) and Ferguson (US 6,972,006 B2 and US2004/0054332A1).

Caillouette fails to disclose the device in accordance with claim 18 wherein at least one indicator projection, which projects from the inner wall of the cylinder and can be overcome by the plunger, is provided at a distance from the bottom of the cylinder.

Ferguson teaches a syringe device comprising at least one indicator projection (tactile ridges, 333), which projects from the inner wall of the cylinder and can be overcome by the plunger (see Figure 3 and Column 5 Lines 29-54), is provided at a distance from the bottom of the cylinder.

Both Caillouette and Ferguson teach syringe devices. Thus, it would have been obvious to a person having ordinary skill in the art at the time of the invention to modify the device disclosed by Caillouette to include indicator projections as taught by Ferguson in order to provide useful tactile feedback to users who are rushed or in low lighting situations, see Ferguson Column 3, Lines 9-16.

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caillouette (US 5,651,372) in view of Bachynsky (US 5,971,953) and DE-20212639 U1 (hereinafter 202').

Caillouette fails to disclose the device of 18 wherein the at least one needle comprises a plurality of needles, at least some of the needles of the needle means have different lengths.

202' teaches a device from removal of fluid from the body comprising a plurality of needles having different lengths, see Figure.

Both Caillouette and 202' teach devices for removal of material from the body. Thus it would have been obvious to a person of ordinary skill at the time of the invention to modify the device disclosed by Caillouette to include a plurality of needles having different lengths as taught by 202' in order to remove material from multiple layers of tissue, which provides for a more comprehensive sampling of a target tissue site.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Response to Arguments

The Applicant's amendment(s), see Drawings, filed 5/29/2008, with respect to Figure 12 overcome the previous objection to the specification. The objection to the specification has been withdrawn.

The Applicant's amendment(s), see Claims, filed 5/29/2008, with respect to Claim 2 overcome the previous claim objections. The objection of claim 2 has been withdrawn.

The Applicant's amendment(s), see Claims, filed 5/29/2008, with respect to Claims 2, 3, 9-11 and 21 overcome the previous 35 USC 112 2nd rejection. The 35 USC 112 2nd rejection of claims 2, 3, 9-11 and 21 has been withdrawn.

Applicant's arguments with respect to claim 18 have been considered but are moot in view of the new ground(s) of rejection.

The Applicant's arguments regarding a device "adapted for aspiration of tissue specimens," is directed to newly presented claim language and is addressed in the rejection above.

The Applicant further argues the claim 18 comprises means for language which evokes 35 U.S.C. 112 6th paragraph.

The Examiner Disagrees.

The limitation "ventilation means" fails to properly identify a 35 U.S.C. 112 6th paragraph limitation. See MPEP 2181 Section I.

Contact Info

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL C. STOUT whose telephone number is (571)270-5045. The examiner can normally be reached on M-F 7:30-5:00 Alternate (Fridays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. C. S./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736